

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

IN RE ANDROGEL ANTITRUST  
LITIGATION (II)

Case No. 09-md-2084-TWT  
END PAYOR CLASS ACTION

GEORGE STEVEN LEGRAND,  
Plaintiff,

v.

UNIMED PHARMACEUTICALS, INC.,  
et al.

Defendants.

Case No. 10-cv-02883-TWT

**DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND  
PADDOCK LABORATORIES, INC.'S ANSWER AND AFFIRMATIVE  
DEFENSES TO PLAINTIFF'S CLASS ACTION COMPLAINT**

Defendants Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc. ("Par/Paddock"), by and through their attorneys, hereby submit their Answer in response to Plaintiff's Class Action Complaint in this matter (the "Complaint"). Defendants file their Answer subject to Plaintiff's acknowledgment that any and all claims contained in Plaintiff's Complaint, including claims pursued under California law, are subject to the Order issued by this Court on February 22, 2010, in which the Court held that "only the sham litigation claim survives" in all consolidated actions. *See* Dkt. No. 50 at 22, *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-md-2084 (N.D. Ga.). Par/Paddock state as follows averring generally

that the responses contained herein are with respect to the allegations directed to Par/Paddock only, as Par/Paddock are not required to respond to allegations put forth against any other Defendants:\*

1. Par/Paddock admit that AndroGel is used for testosterone replacement therapy in men. Par/Paddock deny the remaining allegations in paragraph 1.

2. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 2. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 2 and, therefore, deny the same.

3. Par/Paddock admit that Solvay Pharmaceuticals, Inc. ("Solvay") obtained U.S. Patent No. 6,503,894 (the "'894 Patent") in January 2003. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 3. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

4. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 4. Par/Paddock lack knowledge or information

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\* All references to "paragraphs" and "allegations" refer to the paragraphs and allegations of the Complaint.

sufficient to form a belief concerning the remaining allegations in paragraph 4 and, therefore, deny the same.

5. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 5. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 5 and, therefore, deny the same.

6. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 6 and, therefore, deny the same.

7. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 7. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 7 and, therefore, deny the same.

8. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 8. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 8 and, therefore, deny the same.

9. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 9. Par/Paddock lack knowledge or information

sufficient to form a belief concerning the remaining allegations in paragraph 9 and, therefore, deny the same.

10. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 10. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 10 and, therefore, deny the same.

11. Paragraph 11 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock deny any allegations in Paragraph 11.

12. Paragraph 12 states legal conclusions to which no answer is required.

13. Paragraph 13 states legal conclusions to which no answer is required.

14. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 14 and, therefore, deny the same.

15. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 15 and, therefore, deny the same.

16. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 16 and, therefore, deny the same.

17. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 17 and, therefore, deny the same.

18. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 18 and, therefore, deny the same.

19. Par/Paddock admit that Par is a corporation organized under the laws of Delaware, that it maintains its principal place of business in Woodcliff Lake, New Jersey, and that it is engaged in the development, manufacturing, and marketing of generic drug products. To the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

20. Par/Paddock admit that Paddock is a privately held pharmaceutical company located in Minneapolis, Minnesota and that Paddock is engaged in the development, manufacturing, and marketing of generic drug products.

21. Paragraph 21 states legal conclusions to which no answer is required.

22. Paragraph 22 states legal conclusions to which no answer is required.

23. Paragraph 23 states legal conclusions to which no answer is required.

24. Paragraph 24 states legal conclusions to which no answer is required.

25. Paragraph 25 states legal conclusions to which no answer is required.

26. Paragraph 26 states legal conclusions to which no answer is required.

To the extent an answer may be required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 26.

27. Paragraph 27 states legal conclusions to which no answer is required. To the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

28. Paragraph 28 states legal conclusions to which no answer is required.

29. Paragraph 29 states legal conclusions to which no answer is required.

30. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 30 and, therefore, deny the same.

31. Paragraph 31 states legal conclusions to which no answer is required.

32. Paragraph 32 states legal conclusions to which no answer is required.

33. Paragraph 33 states legal conclusions to which no answer is required.

34. Paragraph 34 states legal conclusions to which no answer is required.

To the extent an answer is required, Par/Paddock deny any allegations in Paragraph 34.

35. Paragraph 35 states legal conclusions to which no answer is required.

To the extent an answer is required, Par/Paddock deny any allegations in Paragraph 35.

36. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 36.

37. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 37 and, therefore, deny the same.

38. Paragraph 38 states legal conclusions to which no answer is required. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 38 and, therefore, deny the same.

39. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 39 and, therefore, deny the same.

40. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 40 and, therefore, deny the same.

41. Par/Paddock admit that Solvay markets AndroGel. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 41 and, therefore, deny the same.

42. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 42 and, therefore, deny the same.

43. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 43 and, therefore, deny the same.

44. Par/Paddock admit that the U.S. Patent Office issued the '894 Patent on January 7, 2003. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 44 and, therefore, deny

the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

45. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 45 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

46. To the extent that Plaintiff's allegations rely on publicly available documents, those documents speak for themselves. To the extent that the allegations in paragraph 46 do not accurately reflect those documents, Par/Paddock deny the allegations in paragraph 46.

47. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 47 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

48. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 48 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.



49. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 49 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

50. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 50 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

51. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 51 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

52. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 52 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

53. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 53 and, therefore, deny the same.

Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

54. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 54 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

55. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 55 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

56. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 56 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

57. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 57 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

58. Par/Paddock admit that the U.S. Patent Office issued the '894 Patent on January 7, 2003. To the extent that Plaintiff's remaining allegations in paragraph 58 rely on a publicly available document, such document speaks for itself.

59. Paragraph 59 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 59 and, therefore, deny the same.

60. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 60 and, therefore, deny the same.

61. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 61 and, therefore, deny the same.

62. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 62 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

63. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 63 and, therefore, deny the same.

Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

64. Paragraph 64 states legal conclusions to which no answer is required.

65. Paragraph 65 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning any allegations in paragraph 65 and, therefore, deny the same.

66. Paragraph 66 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning any allegations in paragraph 66 and, therefore, deny the same.

67. Par/Paddock admit that in 2003, Watson Laboratories, Inc. ("Watson") filed an application with the FDA to market a generic version of AndroGel and that as part of its application, Watson certified that its generic product did not infringe the '894 Patent and that the '894 Patent was invalid. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 67 and, therefore, deny the same.

68. Par/Paddock admit that Unimed Pharmaceuticals, L.L.C. ("Unimed") and Laboratoires Besins Iscovesco ("Besins") filed a patent-infringement lawsuit against Watson, alleging infringement of the '894 Patent.

69. Par/Paddock admit that in 2003, Paddock filed an application with the FDA to market a generic version of AndroGel and that as part of its application, Paddock certified that its generic product did not infringe the '894 Patent and that the '894 Patent was invalid. Par/Paddock also admit that Paddock notified Unimed and Besins that it filed an ANDA containing a Paragraph IV certification.

70. Par/Paddock admit that Paddock and Par partnered for the sharing of costs and risks associated with litigation, together with potential profits if there were a successful outcome, and for Par to market Paddock's generic product. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 70 and, therefore, deny the same.

71. Par/Paddock admit that Unimed and Besins filed a patent-infringement lawsuit against Paddock, alleging infringement of the '894 Patent.

72. Paragraph 72 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning any allegations in paragraph 72 and, therefore, deny the same.

73. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 73 and, therefore, deny the same.

74. Par/Paddock admit that Paddock's ANDA was tentatively approved on October 27, 2004. Par/Paddock admit that Paddock's ANDA received final FDA approval on May 27, 2007.

75. Paragraph 75 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning any allegations in paragraph 75 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

76. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 76 and, therefore, deny the same.

77. Paragraph 77 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning any allegations in paragraph 77 and, therefore, deny the same.

78. Paragraph 78 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information

sufficient to form a belief concerning any allegations in paragraph 78 and, therefore, deny the same.

79. Paragraph 79 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 79 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

80. Paragraph 80 states legal conclusions to which no answer is required.

81. Paragraph 81 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 81 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

82. Paragraph 82 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 82 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

83. Paragraph 83 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 83 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

84. Paragraph 84 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 84 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

85. Paragraph 85 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 85 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on a publicly available document, such document speaks for itself.

86. Paragraph 86 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 86 and,



therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such document speaks for itself.

87. Paragraph 87 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 87 and, therefore, deny the same.

88. Paragraph 88 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 88 and, therefore, deny the same. Furthermore, to the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

89. To the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

90. To the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

91. Par/Paddock admit that the summary-judgment briefing between Paddock and Unimed and Besins was completed by January 19, 2006. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 91 and, therefore, deny the same.

92. Paragraph 92 states legal conclusions to which no answer is required. To the extent an answer is required, Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 92 and, therefore, deny the same.

93. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 93 and, therefore, deny the same.

94. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 94 and, therefore, deny the same.

95. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 95 and, therefore, deny the same.

96. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 96 and, therefore, deny the same.

97. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 97 and, therefore, deny the same.

98. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 98 and, therefore, deny the same.

99. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 99 and, therefore, deny the same.

100. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 100 and, therefore, deny the same.

101. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 101 and, therefore, deny the same.

102. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 102 and, therefore, deny the same.

103. Par/Paddock admit that Unimed, Besins, and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court, the terms of which speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 103 and, therefore, deny the same.

104. Par/Paddock deny the allegations in paragraph 104.

105. Par/Paddock deny the allegations in paragraph 105.

106. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 106. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 106 and, therefore, deny the same.

107. Par/Paddock deny the allegations in paragraph 107.

108. Par/Paddock deny the allegations in paragraph 108.

109. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 109.

110. Par/Paddock admit that Unimed, Besins, and Par/Paddock entered into a written settlement agreement, the terms of which speak for themselves. Par/Paddock deny all remaining allegations in paragraph 110.

111. Par/Paddock admit that Par and Paddock entered into an agreement to transfer title for Paddock's ANDA to Par, the terms of which speak for themselves. Par/Paddock deny all remaining allegations in paragraph 111.

112. Par/Paddock deny the allegations in paragraph 112.

113. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 113 and, therefore, deny the same..

114. Par/Paddock admit that the district court hearing the patent litigation that Unimed and Besins brought against Paddock issued a Consent Judgment and Order of Permanent Injunction in the matter. To the extent the remaining allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 114.

115. To the extent that Plaintiff's allegations rely on publicly available documents, such documents speak for themselves.

116. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 116 and, therefore, deny the same.

117. Par/Paddock admit that Watson and Paddock raised the defense of non-infringement in their respective patent-infringement litigations. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 117 and, therefore, deny the same.

118. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 118 and, therefore, deny the same.

119. Paragraph 119 states legal conclusions to which no answer is required. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 119.

120. Par/Paddock admit that by late 2005, Watson and Paddock had filed motions for summary judgment as well as claim-construction briefs in their respective patent-infringement litigations. Par/Paddock deny the remaining allegations in paragraph 120.

121. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 121 and, therefore, deny the same.

122. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 122 and, therefore, deny the same.

123. Par/Paddock admit that Paddock's ANDA was tentatively approved on October 27, 2004. Par/Paddock admit that Paddock's ANDA received final FDA approval on May 27, 2007. Par/Paddock deny the remaining allegations in paragraph 123.

124. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 124.

125. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 125 and, therefore, deny the same.

126. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 126.

127. Paragraph 127 states legal conclusions to which no answer is required.

128. Paragraph 128 states legal conclusions to which no answer is required.

129. Paragraph 129 states legal conclusions to which no answer is required.

130. Paragraph 130 states legal conclusions to which no answer is required.

131. Paragraph 131 states legal conclusions to which no answer is required.

132. Paragraph 132 states legal conclusions to which no answer is required.

133. Paragraph 133 states legal conclusions to which no answer is required.

134. Paragraph 134 states legal conclusions to which no answer is required.

135. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 135 and, therefore, deny the same.

136. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 136. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 136 and, therefore, deny the same.

137. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 137. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 137 and, therefore, deny the same.

138. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 138. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 138 and, therefore, deny the same.

### **COUNT I**

139. Par/Paddock repeat and reassert all of the responses as if fully set forth herein.

140. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 140.

141. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 141.

142. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 142.

143. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 143.

144. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 144. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 144 and, therefore, deny the same.

145. Paragraph 145 states a legal conclusion to which no answer is required. To the extent the remaining allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 145.

146. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 146.



## **COUNT II**

147. Par/Paddock repeat and reassert all of the responses as if fully set forth herein.

148. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 148.

149. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 149.

150. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 150. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 150 and, therefore, deny the same.

151. Paragraph 151 states a legal conclusion to which no answer is required. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 151 and, therefore, deny the same. Furthermore, to the extent the remaining allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 151.

152. Paragraph 152 states a legal conclusion to which no answer is required.

153. To the extent that such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 153.

### **COUNT III**

154. Par/Paddock repeat and reassert all of the responses as if fully set forth herein.

155. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 155.

156. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 156. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 156 and, therefore, deny the same.

157. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 157.

158. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 158.

159. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 159.

160. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 160.

#### **COUNT IV**

161. Par/Paddock repeat and reassert all of the responses above as if fully set forth herein.

162. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 162.

163. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 163. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 163 and, therefore, deny the same.

164. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 164.

165. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 165. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 165 and, therefore, deny the same.

166. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 166.

167. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 167. Par/Paddock lack knowledge or

information sufficient to form a belief concerning the remaining allegations in paragraph 167 and, therefore, deny the same.

168. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 168.

169. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 169. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 169 and, therefore, deny the same.

#### **COUNT V**

170. Par/Paddock repeat and reassert all of the responses above as if fully set forth herein.

171. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 171.

172. To the extent such allegations apply to Par/Paddock, Par/Paddock deny the allegations in paragraph 172. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 172 and, therefore, deny the same.

#### **DEMAND FOR JURY**

173. This paragraph makes no allegation against Par/Paddock.

### **PRAYER FOR RELIEF**

174. Par/Paddock dispute that Plaintiff is entitled to any relief whatsoever.

Par/Paddock deny each and every allegation of the Complaint not specifically admitted.

Without assuming any burden that it would not otherwise bear, Par/Paddock assert the following affirmative defenses:

#### **FIRST AFFIRMATIVE DEFENSE**

175. Par/Paddock assert that the Complaint fails to state a claim upon which relief may be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

176. Plaintiff's claims are barred, in whole or in part, because under *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), Par/Paddock's actions did not exceed the exclusionary scope of U.S. Patent No. 6,503,894.

#### **THIRD AFFIRMATIVE DEFENSE**

177. Plaintiff's claims are barred, in whole or in part, because the *Noerr-Pennington* doctrine immunizes Par/Paddock for the results achieved by Par/Paddock's successful petitioning of the Court, including the competitive impact of this Court's September 15, 2006 Consent Judgment and Order of Permanent Injunction.

#### **FOURTH AFFIRMATIVE DEFENSE**

178. Plaintiff's claims are barred, in whole or in part, because the *Noerr-Pennington* doctrine immunizes Par/Paddock for the results flowing from the results of Solvay's successful petitioning of the federal government, including the government-granted patent rights. Any alleged harm to Plaintiff occurred due to governmental actions, such as the grant of the '894 patent.

#### **FIFTH AFFIRMATIVE DEFENSE**

179. Plaintiff's claims are barred, in whole or in part, because there are no plausible allegations of harm to competition resulting from Par/Paddock, as the second ANDA filer, entering at the same date as Watson, the first ANDA filer—a more competitive outcome than Congress intended under the Hatch-Waxman regulatory scheme.

#### **SIXTH AFFIRMATIVE DEFENSE**

180. Plaintiff's claims are barred, in whole or in part, because Plaintiff's sham-litigation allegations apply only to Solvay, the plaintiff that initiated the patent-infringement suits, and cannot support a claim against the generic defendants here, who were the defendants and alleged infringers in Solvay's patent suits, particularly where, as here, Par/Paddock filed an ANDA against Solvay's listed drug. Accordingly, even if Plaintiff could state a plausible claim for sham

litigation, it would still fail to state a claim against Par/Paddock.

#### **SEVENTH AFFIRMATIVE DEFENSE**

181. Plaintiff's claims are barred, in whole or in part, because Par/Paddock did not know whether Solvay had a good-faith basis to initiate and maintain its patent infringement litigation against Par/Paddock.

#### **EIGHTH AFFIRMATIVE DEFENSE**

182. Plaintiff's claims are barred, in whole or in part, because Par/Paddock cannot be liable for conspiracy to monopolize because there was no agreement between Par/Paddock and Solvay to monopolize the AndroGel market.

#### **NINTH AFFIRMATIVE DEFENSE**

183. Plaintiff's claims are barred, in whole or in part, because even assuming *arguendo* that the antitrust laws applied and assuming further *arguendo* that the alleged conduct had any potential anticompetitive effect, Par/Paddock's settlement agreement with Unimed and Besins would be governed by the rule of reason under the antitrust laws and is lawful, as its procompetitive benefits outweigh any alleged anticompetitive effect.

**TENTH AFFIRMATIVE DEFENSE**

184. Plaintiff's claims are barred, in whole or in part, because the acts or omissions of Par/Paddock did not substantially lessen competition in any properly defined market.

**ELEVENTH AFFIRMATIVE DEFENSE**

185. Plaintiff's claims are barred, in whole or in part, because Par/Paddock's alleged conduct was reasonable and based on its own independent, legitimate business and economic justifications.

**TWELFTH AFFIRMATIVE DEFENSE**

186. Plaintiff's claims are barred, in whole or in part, because Plaintiff has not suffered injury proximately caused by any conduct of Par/Paddock and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

**THIRTEENTH AFFIRMATIVE DEFENSE**

187. Plaintiff's claims are barred, in whole or in part, because Solvay lacks market power in any properly defined relevant market.

**FOURTEENTH AFFIRMATIVE DEFENSE**

188. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to bring or maintain this action.



**FIFTEENTH AFFIRMATIVE DEFENSE**

189. Plaintiff's claims are barred, in whole or in part, because U.S. Patent No. 6,503,894 is valid, enforceable, and infringed by Par/Paddock's generic testosterone gel.

**SIXTEENTH AFFIRMATIVE DEFENSE**

190. Any and all of Par/Paddock's actions alleged by Plaintiff were lawful, justified, procompetitive, carried out in furtherance of Par/Paddock's legitimate business interests, and constitute *bona fide* competition.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

191. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injury and the injury to competition, if any, is too speculative and uncertain.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

192. Plaintiff's claims are precluded by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984, and related legislation.

**NINETEENTH AFFIRMATIVE DEFENSE**

193. Plaintiff's claims are barred, in whole or in part, because the Complaint fails to provide any economically plausible allegation for Par/Paddock

as the second ANDA filer to have continued to litigate its separate patent-infringement suit, *Unimed Pharms., Inc. et al. v. Paddock Labs., Inc.*, No. 03-cv-02503-TWT (N.D. Ga.), in lieu of settling in 2006, particularly after Watson, the first ANDA filer, settled—especially under the Hatch-Waxman regime as it existed prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003), which governed the ANDAs at issue in this matter.

#### **TWENTIETH AFFIRMATIVE DEFENSE**

194. Plaintiff is barred from recovery of any damages because of and to the extent of its failure to mitigate any such damages.

#### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

195. Plaintiff's claims are barred, in whole or in part, under the *Trinko* doctrine and its progeny because any harm to competition complained of stems from the intricate, multi-tiered regulatory regime that governs the production, sale, and manufacture of pharmaceutical products, including the Hatch-Waxman Act.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

196. Plaintiff's claims are barred, in whole or in part, by the doctrine of *res judicata*.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

197. Plaintiff's claims are barred, in whole or in part, by the doctrine of collateral estoppel.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

198. Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

199. Plaintiff's claims are barred, in whole or in part, for failure to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

200. Plaintiff's claims are barred, in whole or in part, because this action is not properly maintainable as a class action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

201. Par/Paddock reserve the right to amend their Answer or to assert other defenses as this action proceeds.

WHEREFORE, Par/Paddock pray that judgment be entered dismissing the Complaint with prejudice, together with costs, fees, and such other relief as may be just and proper.

Respectfully submitted, this 8th day of November, 2010.

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

IN RE ANDROGEL ANTITRUST  
LITIGATION (II)

Case No. 09-md-2084-TWT  
END PAYOR CLASS ACTION

GEORGE STEVEN LEGRAND,  
Plaintiff,

v.

UNIMED PHARMACEUTICALS, INC.,  
et al.

Defendants.

Case No. 10-cv-02883-TWT

**CERTIFICATE OF SERVICE**

I hereby certify that I have this day electronically filed DEFENDANTS PAR  
PHARMACEUTICAL COMPANIES, INC. AND PADDOCK LABORATORIES,  
INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S CLASS  
ACTION COMPLAINT with the Clerk of Court using the CM/ECF system, which  
will automatically send e-mail notification of such filings to the attorneys of  
record.

Dated: November 8th, 2010

/s/ Mark G. Trigg

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